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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, LISA HYDE and MARK HYDE, a married couple, Plaintiffs, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO PLAINTIFFS LISA AND MARK HYDE'S CLAIMS** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

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MOTION

Pursuant to Fed. R. Civ. P. 56, Local Rule 56.1, and Case Management Order No. 23 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court for partial summary judgment as to certain of the plaintiffs' product liability claims (Counts II, III, VI, VII, VIII, XI, XII, XIII, and XIV) as alleged in the plaintiffs' Short Form Complaint (2:16-cv-00893-DGC, Doc. 1).[1] If Bard's Motion is granted in full, the plaintiffs will be left with claims for negligent design (Count IV), negligence *per se* (Count IX), loss of consortium (Count XV), and punitive damages. For the reasons stated below, Bard is entitled to judgment as a matter of law.

This motion is supported by Defendants' Memorandum of Points and Authorities and Separate Statement of Facts ("SOF") which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Lisa Hyde was treated with a Bard IVC filter in February 2011.[2] Plaintiffs allege that Ms. Hyde's IVC filter is defective because, after it was placed, the filter migrated caudally (towards the feet), tilted, perforated her IVC, and one strut fractured and embolized (moved) to her heart. Ms. Hyde underwent a successful percutaneous

[1] Plaintiffs and Bard have met and conferred regarding the claims that the plaintiffs intend to pursue. Plaintiffs have agreed that they are not pursuing claims for manufacturing defect (Counts I,V) and breach of express warranty (Count X). However, the plaintiffs represented during the meet and confer process that they intend to pursue all of the claims addressed in this Motion.

[2] Plaintiffs bring this product liability action for damages they claim to have suffered as a result of complications Lisa Hyde allegedly experienced related to a Bard G2X IVC filter. Due to the fact that there is no lot number for the IVC filter implanted in Ms. Hyde and the filter was discarded after it was retrieved, there is no way to definitively identify the model of Ms. Hyde's IVC filter. Yet, Bard's IVC filter sales records to the hospital where Ms. Hyde's IVC filter was implanted from the pertinent time period indicate that Ms. Hyde's IVC filter was likely an Eclipse. Whether the filter was a G2X or an Eclipse filter, however, does not bear on Bard's Motion for Summary Judgment.

procedure to remove the IVC filter and the fractured strut. All of the complications that Ms. Hyde alleges were known risks associated with all retrievable IVC filters, and they are risks that Bard specifically warned about in its Instructions for Use for the G2®X and Eclipse® IVC filter, one of which would have accompanied Ms. Hyde's filter.

Bard moves for partial summary judgment under Federal Rule of Civil Procedure 56, and under Wisconsin substantive law, on the following grounds:

A. Strict liability design defect claim (Count III):

   a. Wisconsin presumes that FDA cleared products are not defective and the plaintiffs should not be able to rebut the presumption without a reasonable alternative design.

   b. Wisconsin bars strict liability claims for damages caused by known, inherent characteristics of the product, such as the known and inherent risks that came to pass in Ms. Hyde's filter.

   c. Wisconsin law requires proof of a reasonable alternative design, but the plaintiffs have proffered none.

B. Strict liability failure-to-warn claim (Count II):

   a. Wisconsin presumes that FDA cleared products are not defective and the plaintiffs should not be able to rebut the presumption without a reasonable alternative warning.

   b. Wisconsin bars strict liability claims for damages caused by known, inherent characteristics of the product, such as the known and inherent risks that came to pass in Ms. Hyde's filter.

   c. Wisconsin law requires proof that a reasonable alternative warning would have made the Bard filter "safe," but the plaintiffs have proffered no such alternative warning.

C. Negligent failure-to-warn claim (Count VII):

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a. Bard had no duty to warn under Wisconsin's sophisticated user doctrine because the risks that came to pass in Ms. Hyde's filter were generally known to interventional radiologists.

b. The Instructions for Use that accompanied all of Bard's IVC filters contained warnings about the precise risks of injury that Ms. Hyde experienced, and therefore were adequate as a matter of law.

c. The plaintiffs cannot prove that a specific and different warning would have caused Ms. Hyde's physician to use a different filter because they have offered no such alternative warning and the physician who placed Ms. Hyde's filter testified that he independently knew about the risks at issue.

D. Breach of implied warranty claim (Count XI):

a. Wisconsin does not recognize a breach of implied warranty cause of action in product liability cases.

b. Even if Wisconsin recognized such a claim in a product liability case, there was no privity of contract between Bard and the plaintiffs as would be required.

E. Negligent and fraudulent misrepresentation/concealment claims (Counts VIII, XII, XIII) and claim for Violation of Wisconsin Law (Count XIV):

a. Wisconsin requires proof that the plaintiffs or Ms. Hyde's implanting physician relied on an alleged misrepresentation or omission of material fact by Bard, and the plaintiffs have no such proof.

b. Wisconsin statute 100.18 regarding fraudulent representations requires proof of pecuniary loss from intentionally untrue statements, which the plaintiffs cannot prove.

F. Failure to recall/retrofit (Count VI): Wisconsin does not recognize this as an independent cause of action.

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II. Summary Judgment Standard.

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A moving party without the ultimate burden of persuasion at trial . . . has both the initial burden of production and the ultimate burden of persuasion on a motion for summary judgment." *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102 (9th Cir. 2000). "In order to carry its burden of production, the moving party must either produce evidence negating an essential element of the nonmoving party's claim or defense or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." *Id.* "If . . . a moving party carries its burden of production, the nonmoving party must produce evidence to support its claim or defense." *Id*. at 1130-31 (internal citations omitted).

III. Argument and Citation of Authority.

A. Wisconsin Law Applies to All of Plaintiffs' Claims

Ms. Hyde's IVC filter was placed in Wisconsin, her alleged damages were discovered while she was living in Nevada, and she had the filter removed in California. (SOF, ¶¶ 3, 28, 31.) Plaintiffs filed their short form complaint directly in the MDL and identified the Eastern District of Wisconsin as the forum in which venue would be proper absent direct filing. (2:16-cv-00893-DGC, Doc. 1.) Thus, pursuant to the Court's Second Amended Case Management Order No. 4, Wisconsin's conflict-of-law rules apply in determining whether Wisconsin's or Nevada's law applies.[3] (*See* Doc. 1485.) Likewise, the parties have met and conferred, and agree that Wisconsin choice-of-law rules apply.

Wisconsin's choice-of-law principles weigh heavily in favor of applying Wisconsin law: "[T]he law of the forum should presumptively apply unless it becomes

[3] During the parties' meet and confer process, the plaintiffs claimed that Nevada law should apply, and Bard claimed that Wisconsin law should apply. Because neither party has suggested that California law should apply, because of the state's minimal connection to the case, Bard will not address California in its choice-of-law analysis.

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clear that nonforum contacts are of greater significance." *Drinkwater v. Am. Family Mut. Ins. Co.*, 714 N.W.2d 568, 576 (Wis. 2006) (citation omitted). In Ms. Hyde's case, Nevada's contacts are of no greater significance than Wisconsin's contacts, and therefore Wisconsin law should apply. Indeed, Wisconsin's contacts are more significant than Nevada's contacts in this case:

- The Bard IVC filter that Ms. Hyde received was sold in Wisconsin. (SOF, ¶ 17.)
- Bard's alleged contacts with Ms. Hyde's Wisconsin-based physician occurred in Wisconsin. The plaintiffs have deposed the Wisconsin-based sales representative about these contacts. (*Id.* at ¶ 5.)
- Ms. Hyde's medical treatment leading to the placement of a Bard filter, as well as the placement of the Bard filter, occurred exclusively in Wisconsin while the plaintiffs were residents of Wisconsin. (*Id.* at ¶¶ 1-4.)

In contrast, in 2014, while the plaintiffs were living in Nevada, Ms. Hyde first learned that her IVC filter had fractured. (*Id.* at ¶ 28.) The filter and the strut were removed percutaneously in California. (*Id.* at ¶ 31.)

Thus, Nevada's connections to the facts of this case—which are pure happenstance, as the plaintiffs could have chosen to move, and the filter fracture could have been discovered, anywhere—are not of greater significance to overcome the presumption that Wisconsin law applies. In fact, when compared to Wisconsin's contacts, Nevada's connection to the facts of this case are "so obviously limited and minimal that application of [its] law constitutes officious intermeddling" with the laws of Wisconsin. *Drinkwater*, 714 N.W.2d at 576; *Beloit Liquidating Tr. v. Grade*, 677 N.W.2d 298, 307 (Wis. 2004). Accordingly, Wisconsin law should be applied to the plaintiffs' substantive claims in this case.[4]

[4] Indeed, having identified the Eastern District of Wisconsin as the district of proper venue, if it were not for the MDL, the plaintiffs would be in the odd position of arguing that the law of the state in which they chose to file their case should not apply and that the Wisconsin court should apply Nevada law.

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Because the plaintiffs cannot show that Nevada has significantly greater contacts than Wisconsin to overcome the presumptive application of Wisconsin law, the Court's analysis should end here. *See Extrusion Dies Indus., LLC v. Cloeren Inc.*, No. 08-cv-323-slc, 2008 WL 4401219, at *2, n.2 (W.D. Wis. Sept. 24, 2008). Nevertheless, should the Court proceed to the second step of the analysis, the "choice-influencing factors,"[5] the conclusion that Wisconsin law applies remains the same.

"Predictability of results," which is the first choice-influencing factor, looks at the parties' expectations as to the legal consequences of the conduct which led them to court. *See Drinkwater*, 714 N.W.2d at 577. "In other words, which state's law, if applied, would lead to the more predictable or expected result based on the facts of the case." *Clorox Co. v. S.C. Johnson & Son, Inc.*, 627 F. Supp. 2d 954, 966 (E.D. Wis. 2009). Because Bard's alleged interactions with the physician who placed Ms. Hyde's IVC filter, Dr. Henry, took place in Wisconsin; the plaintiff's IVC filter was sold to a Wisconsin hospital; and the filter was implanted in the plaintiff by Dr. Henry while the plaintiff was a resident in Wisconsin, it is reasonable for both Bard and the plaintiffs to expect that the law of Wisconsin would apply to any claims arising from these interactions. (SOF, ¶¶ 1-5, 17.) Conversely, it is not reasonable for Bard and the plaintiffs to expect that Nevada state law would apply to claims arising from Ms. Hyde's filter implant simply because the plaintiffs happened to move there for reasons unrelated to the IVC filter at issue. (*Id.* at ¶ 30); *see Schultz v. Glidden Co.*, No. 08-C-919, 2013 WL 4959007, at *4 (E.D. Wis. Sept. 13, 2013) (holding, where plaintiff was exposed to benzene-containing products while working in Wisconsin but was later treated and diagnosed in Florida, that Wisconsin law applied where defendant marketed and sold its products to a business in Wisconsin, because application of Wisconsin law was expected, while plaintiff's "move to Florida

[5] These factors include, "(1) Predictability of results; (2) Maintenance of interstate and international order; (3) Simplification of the judicial task; (4) Advancement of the forum's governmental interests; and (5) Application of the better rule of law." *See Extrusion Dies Indus., LLC*, 2008 WL at *2.

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was a fortuitous happenstance, not a predictable result").

"Maintenance of interstate and international order," requires that "a jurisdiction which is minimally concerned defer to a jurisdiction that is substantially concerned." *Drinkwater*, 714 N.W.2d at 577. This is because if "a state that is only minimally concerned with a transaction or tort [] thrust its law upon the parties [it] would be disruptive of the comity between states." *Heath v. Zellmer*, 151 N.W.2d 664, 672 (Wis. 1967). Here, the State of Wisconsin has the stronger interest because an allegedly defective product was sold in Wisconsin and implanted into a Wisconsin resident by a Wisconsin-licensed physician. (SOF, ¶¶ 1-4, 17); *Drinkwater*, 714 N.W.2d at 579 (noting that Wisconsin has a "strong interest in compensating its residents who are victims of torts"). In fact, Wisconsin, in particular, has an even stronger interest than many states would have because less than a month before Ms. Hyde received a Bard Filter, Wisconsin's product liability statute became effective, and the statute applies to all actions for damages caused by a product based on a claim of strict liability, like this case. *See* Wis. Stat. § 895.047. The statute provides the standard by which manufacturers will be judged for claims of design, manufacturing, and warnings defects, and the statute also outlines several defenses for product sellers and/or distributers. *Id.* Thus, in furtherance of the Wisconsin legislature's efforts to provide a comprehensive statutory framework for adjudication of product liability cases, Wisconsin has a strong interest in having its laws apply to a case where the medical device at issue was sold and implanted within Wisconsin's borders. *See, e.g., Stupak v. Hoffman-La Roche, Inc.*, 287 F. Supp. 2d 968, 971 (E.D. Wis. 2003) (holding that Wisconsin has the strongest interest in a medical malpractice and product liability action where the drug was prescribed in Wisconsin because the Wisconsin legislature created a statutory scheme to govern medical malpractice cases); *see also Schultz*, 2013 WL 4959007 at *4 (holding that Florida had no interest in plaintiff's recovery for conduct occurring in Wisconsin "simply because [plaintiff] later became a resident of Florida").

"Simplification of the judicial task" looks to whether application of one state's law over the other would simplify the court's work. *Drinkwater*, 714 N.W.2d at 578. Normally, application of the forum state's law will simplify the court's judicial task except where that law is complex or uncertain as compared to the proposed foreign jurisdiction. *Id.* Here, the MDL court is sitting in place of the transferor court in Wisconsin, so this factor should weigh in favor of applying Wisconsin's law, which is neither complex nor uncertain compared to Nevada's law.

Finally, "advancement of the forum government's interests" and "application of the better rule of law," also weigh in favor of applying Wisconsin law. For the same reasons as "maintenance of interstate and international order," Wisconsin, the forum state, has the most significant government interest in applying its law to this product liability action. *See Sharp v. Case Corp.*, 573 N.W.2d 899 (Wis. Ct. App. 1997) (holding that applying Wisconsin tort law advanced Wisconsin state interests, particularly where, as in Wisconsin, "[t]he law of the forum presumptively applies"), *aff'd sub nom.*, 595 N.W.2d 380 (Wis. 1999). In addition, Wisconsin's adoption of a product liability statute indicates that it considers its legal standards and defenses the better rule of law to be applied in this case. *See Love v. Blue Cross & Blue Shield of Georgia, Inc.*, 439 F. Supp. 2d 891, 896 (E.D. Wis. 2006) ("[I]n a case like this in which the forum state has a clear policy, and when the state's law fairly articulates that policy, it follows that the "better rule of law" will tend to be the forum state's law."). For example, Wisconsin statute 895.047(1)(a) codifies the requirement that a plaintiff establish a "reasonable alternative design" as part of its claim for strict liability design defect, while under Nevada law proof of alternative design is only one factor for the jury to consider. *See Robinson v. G.G.C., Inc.*, 107 Nev. 135, 140 (1991). Accordingly, even based on an analysis of Wisconsin's choice-influencing factors, Wisconsin law should apply to the substantive claims in this case.

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B. Plaintiffs' Strict Liability Design Defect Claim (Count III) Fails for Several Independent Reasons

1. Plaintiff's IVC Filter Was Cleared by the FDA and is Presumed Non-Defective

The Wisconsin product liability statute states that "[e]vidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective." Wis. Stat. § 895.047(3)(b). Bard's IVC filters complied with federal law and the 510(k) process standards and conditions approved by the FDA, a federal agency regarding the filters' design. (SOF, ¶ 25.) Because of Bard's compliance with these federal standards, Bard's IVC filters were cleared for use by the FDA. (*Id.* at ¶ 26.) Without a reasonable alternative design that would have rendered Bard's IVC filter "safe," as discussed below, the plaintiffs should not be able to overcome Wisconsin's statutory presumption. As such, their strict liability design defect claim should fail as a matter of law.

2. Plaintiffs' Alleged Filter Complications Were Inherent and Known Risks of IVC Filters

Wisconsin's product liability statute provides that "[t]he court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product." Wis. Stat. § 895.047(3)(d). All IVC filters, including Bard's IVC filters, carry the risks of fracture, migration, perforation of the IVC, and tilt, which are the risks that came to pass in Ms. Hyde's filter.

By way of example, Ms. Hyde received a Bard filter in February 2011. Ten years earlier, the Society of Interventional Radiology (the national society for physicians who place IVC filters) published clinical practice guidelines that reported about the complications of all IVC filters (indeed, Bard's retrievable filters were not on the market in 2001 when these Guidelines were published). (SOF, ¶ 8-9.) The Society of

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Interventional Radiology reported that IVC filters migrate (reported at rates up to 18%), fracture (reported at rates up to 10%), perforate the IVC (reported at rates up to 41%), and tilt (reported at rates from 5 to 50%). (*Id.*) In 2010, the FDA issued a Safety Alert concerning all IVC filters, entitled, *Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events With Long Term Use*. (*Id.* at ¶¶ 11-12.) The FDA wrote, "Known long term risks associated with IVC filters include but are not limited to lower limb deep vein thrombosis (DVT), filter fracture, filter migration, filter embolization and IVC perforation." (*Id.*) The plaintiffs' expert, Dr. Derek Muehrcke, likewise acknowledges that all IVC filters are known to fracture, migrate, tilt, and perforate the IVC. (*Id.* at ¶ 23.) Finally, Dr. Henry, who is an ordinary user of Bard's IVC filters, testified that at the time of Ms. Hyde's treatment he was aware that IVC filters in general could move, fracture, and that fractured components could embolize. (*Id.* at ¶ 14.) Thus, the complications that came to pass in Ms. Hyde's filter are inherent characteristics of IVC filters and were widely known and discussed before Ms. Hyde received a Bard filter in 2011. Accordingly, the plaintiffs' strict liability claims should be dismissed under Wisconsin Statute § 895.047(3)(d).

3. Plaintiffs Lack Evidence of a Reasonable Alternative Design

To establish a strict liability design defect, plaintiffs must prove, through expert testimony, that "the foreseeable risks of harm posed by the [plaintiff's IVC filter] could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." *See* Wis. Stat. § 895.047(1)(a); *Johnson v. Mylan Inc.*, 107 F. Supp. 3d 967, 974 (E.D. Wis. 2015) (expert testimony required when matters are outside a lay jury's common knowledge or ordinary experience).

In this case, Ms. Hyde was treated with a Bard retrievable IVC filter. Thus, one of the primary design elements of the filter was that it could be percutaneously removed at the physician's option. In fact, Dr. Henry testified that the Bard filter's ability to "potentially be retrieved" was "definitely" one of the benefits that he considered in

choosing the Bard filter for Ms. Hyde. (SOF, ¶ 7.) The plaintiffs, however, have not identified a reasonable alternative design to the Bard filter that Ms. Hyde received that reduces or avoids the alleged complications that she experienced while also retaining the option of percutaneous retrieval.[6] Accordingly, because the plaintiffs cannot establish a reasonable alternative design to the filter that Ms. Hyde received, their strict liability design defect claim fails as a matter of law under Wis. Stat. § 895.047(1)(a).

C. Plaintiffs' Strict Liability Failure-To-Warn Claim (Count II) Fails Because of Wisconsin's Statutory Defense and for Lack of Evidence

As discussed, *supra*, the Wisconsin product liability statute provides a rebuttable presumption that products are not defective when they complied with standards adopted or approved by a federal agency, like the FDA. Wis. Stat. § 895.047(3)(b). Here, Bard's Instructions for Use ("IFU") documents, which accompanied its IVC filters and contained warnings about the filters' risks, were submitted to and cleared by FDA. (SOF, ¶¶ 19-21, 25-26.) Thus, Bard should be entitled to a presumption that the warnings were not defective. And because the plaintiffs have not identified any language that would have cured the alleged defective warnings, as discussed below, they should not be permitted to overcome the presumption of no defect. As such, the Court should grant summary judgment on the plaintiffs' strict liability failure-to-warn claim.

Similarly, the Wisconsin product liability statute bars strict liability claims where the damage to the plaintiff is caused by a known and inherent characteristic of the product. Wis. Stat. § 895.047(3)(d). As discussed, *supra*, the complications that came to pass in

[6] To the extent that the plaintiffs claim that the Simon® Nitinol Filter ("SNF") is a reasonable alternative design, the argument fails because the filter cannot be retrieved. *See Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 743 N.W.2d 159, 162 (2007), *aff'd as modified*, 768 N.W.2d 674 (2009) (noting that an alternative design cannot make the product "something else."); *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) (finding that regular bullets were not a feasible alternative design for hollow-point bullets because the expansion mechanism of the hollow-point bullets "was an intentional and functional element of the design of the product."). In addition, the plaintiffs' expert, Robert M. McMeeking, Ph.D., testified that the SNF does not represent a reasonable alternative design to Bard's retrievable IVC filters. (SOF, ¶ 32.)

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Ms. Hyde's filter are inherent characteristics of IVC filters that were known and discussed before Ms. Hyde received a Bard filter in 2011. As such, the plaintiffs' strict liability failure-to-warn claim fails as a matter of law.

Finally, to establish a prima facie strict liability failure-to-warn claim, the plaintiffs must prove that "the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Satisfying this element of proof requires reasonable alternative warnings that would have rendered Bard's filter "safe." *See Lexington Ins. Co. v. Whesco Grp., Inc.*, No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013) (noting that a strict liability warnings claim requires proof of reasonable alternative warnings and granting summary judgment to the defendant manufacturer on this claim). The plaintiffs, however, have identified no such alternative warnings. As such, the plaintiffs cannot meet their burden of proof and summary judgment is warranted.

D. Plaintiffs' Negligent Failure-To-Warn Claim (Count VII) Fails for Several Independent Reasons

1. Under Wisconsin's Likely Adoption of the Learned Intermediary Doctrine and the Sophisticated User Doctrine, Bard Had No Duty To Warn

Although the Wisconsin Supreme Court has not yet had the opportunity to address the learned intermediary doctrine, multiple federal courts applying Wisconsin law have held that a medical device manufacturer's duty to warn runs to the treating physician rather than to the patient. *See, e.g., Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273 at *20 (E.D. Wis. May 12, 1999) (applying Wisconsin law, holding that under the learned-intermediary doctrine, "the manufacturer must warn the physician . . . and not the patient directly"); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law) ("under the Learned Intermediary Doctrine,

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manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product"); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981), *amended*, 532 F. Supp. 211 (E.D. Wis. 1981). Further, a Wisconsin state trial court has followed this rule and recognized that "courts of numerous other jurisdictions almost universally hold that in the case of prescription drugs, a manufacturer's provision of proper warnings to a prescribing physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug except through the physician." *Straub v. Berg*, Nos. 00-CV-2100, 00-CV-0117, 2003 WL 26468454 at *6 (Wis. Cir. Jan. 6, 2003) (citation omitted). Thus, in this case, any duty that Bard had to warn ran to Ms. Hyde's treating physician, not to Ms. Hyde.

Moreover, under Wisconsin's application of the sophisticated user doctrine, "there is no duty to warn members of a trade or profession about dangers generally known to that trade or profession." *Shawver v. Roberts Corp.*, 280 N.W.2d 226, 233 (Wis. 1979). Thus, there is "no duty to warn if the user knows or should know of the potential danger, especially when the user is a professional who should be aware of the characteristics of the product." *Haase v. Badger Mining Corp.*, 669 N.W.2d 737, 743 (Wis. Ct. App. 2003) (citation omitted).

Here, the sophisticated user doctrine bars the plaintiffs' negligent failure-to-warn claim because at the time of Ms. Hyde's treatment with a Bard IVC filter, the risks that came to pass in Ms. Hyde were known risks associated with IVC filter generally, including with Bard IVC filters. As discussed, *supra* in Section B.2, the Society of Interventional Radiology had published about these risks of IVC filters as early as 2001, the FDA described these as "[k]nown long term risks associated with IVC filters" in 2010, the plaintiffs' expert acknowledges that these risks exist with all IVC filters, and Dr. Henry testified that he knew the risks when he placed the Bard filter in Ms. Hyde. (SOF, ¶ 8-9, 11-12, 14, 23.) Moreover, by 2011, the medical literature contained numerous articles discussing Bard filters and the risks that came to pass in Ms. Hyde's filter. (*See, e.g., Id.* at ¶ 10, 13) (discussing an article published in 2010 reporting on the

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complications of strut fracture and embolization to the heart in several patients with Bard's filters; and an article published in 2009 reporting on perforation, filter fracture, tilt, and migration with Bard's filters). Thus, the risks inherent in IVC filters were "generally known to that trade or profession." Accordingly, Bard had no duty to warn of these complications pursuant to the sophisticated user doctrine, and summary judgment is warranted on the plaintiffs' negligent failure-to-warn claim.

2. Bard's Warnings Were Adequate as a Matter of Law

Even if Bard had a duty to warn about the risks inherent in its IVC filters, Bard's warnings to physicians through the IFUs, which accompanied each IVC Filter, were adequate as a matter of law. Bard's IFUs contain specific warnings regarding the risks of migration, tilt, perforation, strut fracture, and cardiac complications requiring retrieval of the fragment percutaneously or surgically, which are the complications that Ms. Hyde experienced.

Under two separate bolded headings, "**Warnings**" and "**Potential Complications**" the IFUs contain the following language about filter fracture and embolization:

> **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**

(SOF, at ¶ 19) (emphasis in original.)

Under the same two separate bolded headings, the IFUs contain the following language about filter migration and tilt:

> **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots, and/or dislodgement due to large clot burdens.**

(*Id.*) The "**Potential Complications**" section also warns about "Filter tilt" and "Filter malposition." (*Id.* at ¶ 20.)

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Under the bolded "**Potential Complications**" section, the IFUs also warn about perforation of the IVC wall: "Perforation or other acute or chronic damage of the IVC wall" and "Vessel injury." (*Id.*)

Finally, the IFUs warn that "**All of the above complications may be associated with serious adverse events such as medical intervention and/or death.**" (*Id.* at ¶ 21).

Because the IFU warned Dr. Henry about the precise risks of complications that came to pass with Ms. Hyde's IVC filter, Bard's warnings were legally adequate. *See, e.g., Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 878 (Wis. Ct. App. 2004) (affirming that Warner-Lambert's warnings were adequate as a matter of law when they discussed the precise complications that the plaintiff experienced); *see also, e.g., Below by Below v. Yokohama Tire Corp.*, No. 15-CV-529-WMC, 2017 WL 570985, at *2 (W.D. Wis. Feb. 13, 2017) (holding that warning was adequate as a matter of law when it warned of the specific danger that occurred in the case); *Lemmermann v. Blue Cross Blue Shield of Wis.*, 713 F. Supp. 2d 791, 811, 813 (E.D. Wis. 2010) (same).

To the extent the plaintiffs argue that Bard failed to warn Dr. Henry regarding the relative complication rates of Bard's IVC filters compared to other filters, Bard can find no Wisconsin law creating such a duty. Rather, courts that have addressed the issue have found that pharmaceutical and medical-device manufacturers have no such duty to warn.[7] Likely for this reason, Bard could find no IVC filter manufacturer that provides comparative rates in the instructions for use that they provide to doctors. (SOF, ¶ 24.) Accordingly, Bard had no legal duty to provide warnings to Dr. Henry regarding the rates of complications with its IVC filters in comparison to any other IVC filter.

[7] *See, e.g., Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 291–92 (6th Cir. 2015) (affirming summary judgment on failure-to-warn claim where the lower court rejected the plaintiff's argument that the product labeling did not warn that the risk of stroke for the birth control at issue was higher than with other birth control products); *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) ("The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug . . . . It is not obligated to provide a comparison of its drug with others").

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3. Any Alleged Failure To Warn Was Not the Proximate Cause of Plaintiffs' Alleged Injuries

An element of the plaintiffs' negligent failure-to-warn claim requires proof that the inadequate warning caused their alleged damages.[8] *See Kessel ex rel. Swenson v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211 (Wis. Ct. App. 2006). Wisconsin's standard for causation is "whether the defect was a substantial factor in producing the injury." *Solar v. Kawasaki Motor Corps, U.S.A.*, 221 F. Supp. 2d 967, 970 (E.D. Wis. 2002); *see also Werner v. Pittway Corp.*, 90 F. Supp. 2d 1018, 1027 (W.D. Wis. 2000). In the context of prescription medical products, satisfying this burden requires proof that the purported proper warning would have caused a different product to be used, thereby avoiding the plaintiff's alleged injuries. *See Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) ("Absent proof that a more complete or explicit warning would have prevented [plaintiff's] use of [defendant's product], she cannot establish that [defendant's] alleged failure to warn was the proximate cause of her injuries.); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law, and finding that "a plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff").

Here, Ms. Hyde's treating doctor never testified that if he had received a different warning for Bard's IVC filter, he would have chosen a different filter. Rather, he testified that his criteria for choosing an IVC filter was that it was cleared for use by the FDA, that he trusts the FDA more than individual manufacturers, and that he would not have altered his treatment of Ms. Hyde with a Bard IVC filter even if he was provided with certain facts the plaintiffs allege to be true. (SOF, ¶ 15.) In the absence of evidence establishing that an alleged failure to warn was the cause of the plaintiffs' injuries—that is, that a

[8] Proof of causation also applies to the plaintiffs' strict liability failure-to-warn claim. Wis. Stat. § 895.047(1)(e). As such, summary judgment is warranted on the plaintiffs' strict liability failure-to-warn claim on this ground too.

different warning would have caused Ms. Hyde's physician to use a different filter—the plaintiffs cannot satisfy the causation element of their failure-to-warn claims. *See Kurer*, 679 N.W.2d at 876 (affirming summary judgment on the plaintiff's failure-to-warn claim where the plaintiff failed to establish that any additional warning would have prevented her alleged harm).

Likewise, Dr. Henry testified that before he treated Ms. Hyde, he was already aware that IVC filters carried the risks that came to pass in Ms. Hyde: "At the time that you implanted the Bard filter in Mrs. Hyde, I think you've testified that you were aware that complications with filters included movement of the filter, fracture, and even embolization or movement of a fractured fragment; is that true? A. Yes." (SOF, ¶ 14.) Because Dr. Henry already knew about the potential complications that occurred in Ms. Hyde's filter, no alleged failure to warn about those potential complications could have proximately caused Ms. Hyde's alleged injuries.

E. Plaintiffs' Breach of Implied Warranty Claim (Count XI) Fails Because Wisconsin Does Not Recognize The Cause of Action in Product Liability Cases

Wisconsin does not recognize a product liability cause of action for breach of implied warranty. *Austin v. Ford Motor Co.*, 273 N.W.2d 233, 240 (Wis. 1979) (finding that under Wisconsin law "it is inappropriate to bring an action for breach of warranty where a tort remedy is sought"). Thus, tort and breach of implied warranty claims may not be brought in the same action. *Id.* at 241 ("[P]laintiffs [can] not encumber the case by trying it on the duplicative theories of strict product liability and implied breach of warranty."). Accordingly, because the plaintiffs filed claims against Bard sounding in tort, they are precluded from also pursuing a breach of implied warranty claim. *See, e.g.*, *Adamany ex rel. Adamany v. Cub Cadet Corp.*, No. 04-C-02240C, 2004 WL 1795237, at **1-2 (W.D. Wis. Aug. 5, 2004) (dismissing plaintiffs' breach of implied warranty claim finding that plaintiffs could not pursue an action for strict products liability and for breach of implied warranties).

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Even if the plaintiffs' breach of implied warranty claim against Bard was viable, a prima facie breach of implied warranty claim requires privity of contract. *Northridge Co. v. W.R. Grace & Co.*, 471 N.W.2d 179, 187 (Wis. 1991). Here, the plaintiffs were not in privity of contract with Bard because Bard's IVC filters are not sold directly to patients and the plaintiffs cannot produce any evidence that they are the "buyer" of Ms. Hyde's IVC filter from Bard. (SOF, ¶¶ 17-18.) As such, even if a breach of implied warranty claim were permitted, the plaintiffs cannot satisfy an element of the claim.

F. Plaintiffs' Negligent and Fraudulent Misrepresentation/Concealment Claims (Counts VIII, XII, XIII) and Claim for Violation of Wisconsin Law Claim (Count XIV) Fail as a Matter of Law Because Plaintiffs Cannot Prove the Essential Elements of Reliance or Causation

To establish a claim of negligent or fraudulent misrepresentation, the plaintiffs have the burden to prove that they acted in reliance upon a false representation by Bard. *See Kohler Co. v. Kopietzki*, No. 13-cv-1170, 2016 WL 1048036, at *6 (E.D. Wis. Mar. 11, 2016); *Grube v. Daun*, 496 N.W.2d 106, 115 (Wis. Ct. App. 1992). Similarly, to succeed on a fraudulent concealment claim, the plaintiffs must prove that they acted in reliance on Bard's material factual omission. *See Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998).

Here, the plaintiffs both testified that they have never spoken to anyone at Bard or received any information from Bard, (SOF, ¶ 27), and therefore could not have acted in reliance on anything that Bard allegedly said or omitted. Moreover, Dr. Henry testified that he relied on information from the FDA, not Bard, when he chose to use Bard's IVC filter for Ms. Hyde. (*Id.* at ¶ 15). And he did not recall any discussions with Bard's sales representatives that occurred at any time before treating Ms. Hyde. (*Id.* at ¶ 16.f) Thus, the plaintiffs cannot prove that Dr. Henry acted in reliance on anything that Bard allegedly said or omitted in communications to him, and the plaintiffs' claims for negligent and fraudulent misrepresentation fail as a matter of law.

Similarly, a claim under Wisconsin statute 100.18 for fraudulent representations requires the plaintiffs to show that they sustained a pecuniary loss as a result of intentional untrue statements made to the public. Wis. Stat. § 100.18. Here, there is no evidence that any alleged intentional untrue statements that Bard made to the public caused Dr. Henry to use the Bard IVC filter or the plaintiffs to incur any pecuniary loss. *See Valente v. Sofamor, S.N.C.*, 48 F. Supp. 2d 862, 874 (E.D. Wis. 1999) (claim under Wisconsin Statute § 100.18 fails because no causal connection between defendant's alleged conduct and any pecuniary loss suffered by the plaintiffs). As such, the claim fails as a matter of law.

G. Plaintiffs' Claim for Failure to Recall/Retrofit (Count VI) Fails Because Wisconsin Does not Recognize This Claim as an Independent Cause of Action

Plaintiffs' claim for failure to recall/retrofit is premised on Bard's purported breach of its duty to recall or retrofit Bard's IVC filters (See Master Complaint for Damages for Individual Claims [Dkt. No. 364] at ¶¶ 206-209). Yet, no Wisconsin statute or court has recognized that a manufacturer has an independent duty to recall or retrofit a product. Because Wisconsin does not recognize an independent cause of action to recall or retrofit a product, the plaintiffs' claim fails as a matter of law.

IV. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Partial Summary Judgment.

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.

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